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Attorney Docket No.: 601-017c1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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In re application of
Zohoungbogbo et al.

Examiner: Hui

Serial No: 09/982,554

Art unit: 1617

Filed: October 18, 2001

For: DIETETIC FOOD COMPOSITION

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REQUEST FOR REHEARING
DECISION APPEAL DATED FEBRUARY 12, 2009

Mail Stop Appeal -PATENTS

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sirs:

In response to the Decision on Appeal dated February 12, 2009, please enter the following remarks requesting a rehearing. A Request for a One Month Extension of time through May 12, 2009 was granted/mailed on April 15, 2009.

As per 37 CFR 41.52(a)(1), the Request for Rehearing was authorized by the Board of Patent Appeals and Interferences on Page 13 of the decision on Appeal because the decision was termed a "new ground of rejection."

Appellant affirms that there is no new evidence presented in this Request for Rehearing. Appellant notes that on page 9 of the Decision on Appeal in footnote 14, the April 16, 2003 Declaration of Mr. Zohoungbogbo was not attached to the Brief.

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Appellant attaches a copy hereto as Exhibit 1. As this Declaration is already in the application record as it was originally submitted with the June 16, 2003 Amendment, it does not constitute new evidence.

Summary of Appeal and Decision on Appeal

Brief Appeal Summary

In the Appeal, Appellant argues that the Examiner's rejection of the claims was in error. Appellant, among other arguments, contends that independent claim 45 is improperly rejected under 35 U.S.C. § 103(a) as being unpatentable over Marquie et al. (Life Sciences, 1998; 63(1):65-67), Pentikainen et al. (Annals of Medicine, 1990;22:307-312), and Poupon et al. (Heptology, 1993;17(4):577-582) in view of Spasmo-Canulase® Bitlab ® package insert (July 1989), and Krause et al. (Food Nutrition, and Therapy, 7th ed. 1984, page 656-658, W.B. Saunders Company).

Without re-submitting the full arguments from the Appeal Brief in this Request for Rehearing, Appellant argues that the cited references do not teach or suggest all of the elements of the present invention as claimed in independent claim 45, nor is there any suggestion or motivation to combine the references with one another. Furthermore, Appellant claimed that it is not *prima facia* obvious to combine the reference under the law as set forth in *In re Kerkhoven* (205 USPQ 1069) as suggested by the Examiner.

The Examiner, in his counter-argument continuing his argument from the prior Office Actions, claims that:

"the references do not expressly teach the method of treating the side effects of a ketogenic diet with the combination of benfluorex, metformin, and ursodesoxycholic acid. The references do not expressly teach the herein claimed amount ratio employed.

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The references do not expressly teach the employment of pancreatin and sodium dehydrocholate with benfluorex and metformin. The references do not expressly teach the dosage of the composition herein claimed as 7g to 23g. The references do not expressly teach the method further include steps that replace the food composition in form of a flour having more than 20% carbohydrates by weight and determine the patients whether is suffering from the side effects of ketogenic diet [sic]

Spasmo-Canulase Bitab package insert teaches Spasmo-Canulase Bitab which contains pancreatin and sodium dehydrocholate, is useful in treating abdominal cramps associated with flatulence. [sic]

Krause et al teaches ketogenic diet as approximately 90% of calories are from fat and only around 11% of calories are from proteins and carbohydrates (page 657, col. 1-2) [sic]

The Examiner goes on to state that it would have been obvious to combine the teachings of these five references to arrive at the present invention as claimed in independent claim 45.

Brief Summary of Decision on Appeal

In the Decision on Appeal the Board agreed with the Examiner's argument, at least with regard to independent claim 45, about the obviousness to combine a hypocholesterolemic agent (benfluorex), a hypoglycemic agent (metformin) and a ursodesoxycholic acid under both *KSR* 127 S.Ct. at 1734; *Graham*, 383 U.S. at 17 and *Kerkhoven* 626 F.2d at 850.

However, the Board went on to indicate that the Examiner *did not* successfully make a *prima facie* case for obviousness regarding the incorporation of pancreatin and sodium dehydrocholate with a composition containing metformin.

The Board however, articulates its own reasoning for sustaining the obviousness rejection (new grounds). The Board concludes on pages 10 and 11 of the decision that:

We find that Pentikainen discloses side effects were common with

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metformin use and that those side effects included gastrointestinal pains and meteroism (FF 7). Meteroism is defined as “tympanites; distension of the abdomen with gas” and flatulence is defined as “the presence of an excessive amount of gas in the stomach and intestines.” *Since Pentikainen teaches that abdominal cramps (gastrointestinal pains) and flatulence (meteorism) are common side effects of taking metformin, there is a sufficient factual basis to conclude that it would have been prima facie obvious to include pancreatin and sodium dehydrocholate in a cholesterol lowering composition containing metformin.*

Furthermore, the fact that the Examiner’s reason for incorporating pancreatin and sodium dehydrocholate is not the same as Appellant’s alternative reason is sufficient to rebut the conclusion of obviousness presented by the Examiner. KSR, 127 S.Ct. at 1741; In re Dillion, 919 F.2d 688, 693-94 (Fed. Cir. 1990). It is settled law that the teaching or suggestion to combine references’ disclosures need not be explicitly stated in the prior art, but may be implicit from the state of prior art considered as a whole. In re Kahn, 441 F.3d 977, 987 (Fed. Cir. 2006); cited with approval in KSR, 127 S.Ct. at 1741.

Thus, we conclude that, based on the totality of new factual basis above, the subject matter of claim 45 is prima facie obvious over the combined teachings of Marquie, Pentikainen, Poupon, Spasmo-Canulase, and Krause. (emphasis added)

Statement of points believed to be overlooked and misapprehended by the Board

Appellant respectfully submits that the Board of Patent Appeals and Interferences erred in sustaining the rejection and contends that even if each of the references independently teach certain elements of the claims, there is no teaching or suggestion, nor is it implicit within the art, to combine the reference to arrive at the present invention as claimed in independent claim 45.

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Arguments

Appellant submits that the reason for combining the references as suggested by the Board in their modified obviousness rejection is insufficient to meet the requirements to find the elements of claim 45 obvious.

Appellant notes that:

"[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, *there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness*". KSR, 127 S.Ct. at 1741. (emphasis added) cite from In re Kahn

Although KSR has acknowledged that there is no a rigid test that requires the Examiner/Board to indicate the teaching, motivation or suggestion to combine, within the references themselves, for forming the obviousness rejection, it has not removed the requirement for articulating *why* one of ordinary skill in the art would combine the references to reach the specific combination as claimed.

In the present application, it appears that both the Examiner and the Board are using the present claim as a blueprint and working backwards to find various components from disparate references to form the rejection.

Knowledge of a problem and motivation to solve it are entirely different from motivation to combine *particular references to teach the particular claimed method*. An obviousness rejection should not be sustained using hindsight reconstruction of references to reach the claimed invention without explanation as to how or why the *particular references would be considered to be combined to reach the elements of the claims*. *Innogenetics, N.V. v. Abbott Laboratories*, 512 F.3d 1363 at footnote 3.

In the present application, the claims recite a compound having a multiple

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elements, each provided in their own concentrations. Although each of the substances themselves may be independently considered to be known in the art, when evaluating the claim for obviousness, the claim must be taken in its totality, including the totality of the combined substances and the claimed ranges for each of those substances.

For example, as noted above, the Board recites that Pentikainen teaches that abdominal cramps (gastrointestinal pains) and flatulence (meteorism) are common side effects of taking metformin (another element in the claim.) On those grounds, the Board then concludes that it would be obvious to include pancreatin and sodium dehydrocholate to avoid these conditions.

However, it is noted that metformin as well as benfluorex and ursodesoxycholic acid may have many different side effects, and that there are numerous manners in which to treat them. In the present claim 45 however, the Appellant claims a specific lipasic and proteasic agent of pancreatin IX F.U. (present in the amount from 27% to 43% in weight of the total amount of the composition) as well as a hydrocholeretic agent selected from the group consisting of (at least) Na dehydrocholate (present in the amount from 9% to 14% in weight of the total amount of the composition).

Thus not only were specific agents selected to treat specific side effects, but they were added within limited ranges. As noted in the specification, the ranges work, particularly in combination with the other components and the ranges claimed for them. Appellant acknowledges that for each component taken alone, there may be existing dosage knowledge, with routine experimentation needed to select one. However, the ranges claimed are for several claimed components and the requirement to show obviousness, must render obvious the relative concentrations to one another as that is

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what claim 45 is claiming, among other elements.

As such, to form an obviousness rejection of claim 45, the cited references should not only mention individual components and potential dosages, but instead taking the claim in its totality, must suggest to one of ordinary skill art to combine each of the claimed components and in their percentage weight, present relative to the total amount of the composition

In view of the foregoing, Appellant respectfully submits that Board and Examiner have erred in finding the claims of the present application obvious over the cited references and requests that the Board of Appeals and Interferences re-hear the prior arguments set forth in the Appeal Brief *further in view of the clarifications and arguments set forth above in this Request.*

Dated:
5/11/09

Respectfully submitted
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